PATENT

Customer No. 22,852

Attorney Docket No. 09395-0001 Application No.: 10/822,938

N THE UNITED STATES PA	ATENT AND	TRADEMARK	<b>OFFICE</b>
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In re Application of:	)
Chin Ying HSIAO et al.	) Group Art Unit: 1653
Application No.: 10/822,938	) Examiner: S. M. Noakes
Filed: April 12, 2004	) Confirmation No. 4416
For: NOVEL COLLAGEN PRODUCTION METHOD	) ) )
Commissioner for Patents Washington, DC 20231	
Sir:	

## **DECLARATION UNDER 37 C.F.R. § 1.132**

- I, Seah June Nam, Ph.D., do hereby make the following declaration:
- 1. I am an inventor of the subject matter of this application and am employed as the Chief Scientific Officer with EcoDynamic BioLab.
- 2. I received my Masters of Science in 1994 from Yang Ming Medical University, Graduate School of Microbiology and Immunology. In 2002, I completed a doctorate in microbiology and immunology at the National University of Singapore, Temasek Life Sciences Laboratory. I have published several peer-reviewed journal articles in the area of microbiology. A copy of my curriculum vitae is attached as Exhibit A to this declaration.
- 3. My duties at EcoDynamic BioLab include the development of methods to isolate collagen for therapeutic purposes. I am familiar with methods for the isolation of

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collagen and have attempted to isolate collagen from various collagen-containing

tissues.

4. I have reviewed the pending claims and specification of this application, which

clearly details the isolation of collagen monomers from various tissue sources using

microbial fermentation.

5. I have read and am familiar with the Office's rejection of claims 54-78 for lack

of enablement, as set forth in the Advisory Action of May 22, 2007, the Office Action of

October 6, 2006, and the Office Action of April 20, 2006.

6. My own research at EcoDynamic BioLab in this area demonstrates that the

invention is enabled. The methodology detailed in Example 3 of the specification (pp.

21-22) was used to isolate collagen monomers from porcine tissue. Four different

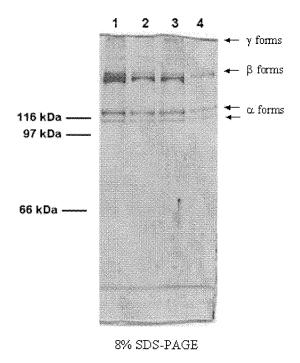
bacterial strains were tested: Bacillus subtilis, Bacillus pumilus, Pseudomonas

aeruginosa (ATCC 27853), and Escherichia coli (ATCC 10798).

7. All four bacterial strains were effective in isolating collagen monomers, as

evidenced by the SDS-PAGE gel in the figure below.

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Lane 1 Bacillus subtilis Lane 2 Bacillus pumilus Lane 3 Pseudomonas aeruginosa Lane 4 Escherichia coli

8. Based upon these data and my own experience and my study of the above, it is my belief and professional opinion that one of ordinary skill in the art could practice the claimed methods using the guidance provided in the specification. The five examples in the specification and the experiments detailed above demonstrate that undue experimentation would not be required to determine what species of microorganism will work with the claimed invention.

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9. I hereby declare that the foregoing statements of fact set forth above are true, and that all opinions are believed to be true.

Dated: NN.5- 2007

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Dr. Seah June Nam